



European Patent  
Office

**PARTIAL EUROPEAN SEARCH REPORT**  
which under Rule 45 of the European Patent Convention  
shall be considered, for the purposes of subsequent  
proceedings, as the European search report

Application number

EP 89 10 5476

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
X	US-A- 3 657 744 (ERSEN) <i>A61B 17/11</i>		
	* Abstract; column 3, lines 41-55; figures 3,4 *	25,29	
Y	--	33-36	A 61 F 2/06
Y	EP-A-0 274 846 (ROSENBLUTH) <i>B61F 2/05</i>		
	* Claim 1; figures *	33-36	
	--		
A	EP-A-0 177 330 (COOL INCORPORATED) <i>"</i>		
	* Figures 7,8; page 6, lines 16-24 *	25,29	
	--		
D,A	EP-A-0 221 570 (PALMAZ) <i>"</i>		
	-----		
			TECHNICAL FIELDS SEARCHED (Int. Cl. 4)
			A 61 F A 61 M A 61 B
<b>INCOMPLETE SEARCH</b>			
<p>The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims.</p> <p>Claims searched completely: 25-36 Claims searched incompletely: Claims not searched: 1-24 Reason for the limitation of the search:</p> <p>Method for treatment of the human or animal body by surgery or therapy (see art. 52(4) of the European Patent Convention).</p>			
Place of search The Hague		Date of completion of the search 06-06-1989	Examiner STEENBAKKER
<b>CATEGORY OF CITED DOCUMENTS</b>			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons Δ : member of the same patent family, corresponding document	

## PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

United States Patent and Trademark  
Office  
(Box PCT)  
Washington D.C. 20231  
United States of America

in its capacity as elected Office

Date of mailing (day/month/year)

21 December 1995 (21.12.95)

International application No.

PCT/US95/06228

Applicant's or agent's file reference

S63.3-5519

International filing date (day/month/year)

18 May 1995 (18.05.95)

Priority date (day/month/year)

19 May 1994 (19.05.94)

Applicant

BURMEISTER, Paul, H. et al

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

11 December 1995 (11.12.95)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

J. Leitao

Telephone No.: (41-22) 730.91.11

## PATENT COOPERATION TREATY

PCT

COMMUNICATION OF  
INTERNATIONAL APPLICATIONS

(PCT Article 20)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark  
Office  
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Washington D.C. 20231  
United States of America

Date of mailing:

01 February 1996 (01.02.96)

in its capacity as designated Office

The International Bureau transmits herewith copies of the international applications having the following international application numbers and international publication numbers:

International application no.:

PCT/US95/06228

International publication no.:

WO95/31945

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer:

J. Zahra

Telephone No.: (41-22) 730.91.11

PCT

From the INTERNATIONAL BUREAU

NOTICE INFORMING THE APPLICANT OF THE  
COMMUNICATION OF THE INTERNATIONAL  
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:

ARRETT, Oliver, F.  
Vidas, Arrett & Steinkraus  
Suite 1540  
920 Second Avenue South  
Minneapolis, MN 55402  
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)

01 February 1996 (01.02.96)

Applicant's or agent's file reference

S63.3-5519

## IMPORTANT NOTICE

International application No.

PCT/US95/06228

International filing date

18 May 1995 (18.05.95)

Priority date

19 May 1994 (19.05.94)

Applicant

SCIMED LIFE SYSTEMS, INC. et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

CA,EP,JP,US

2. In accordance with Rule 47.1(c), third sentence, each designated Office will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Offices.
3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 30 November 1995 (30.11.95) under No. WO 95/31945

## REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

## REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

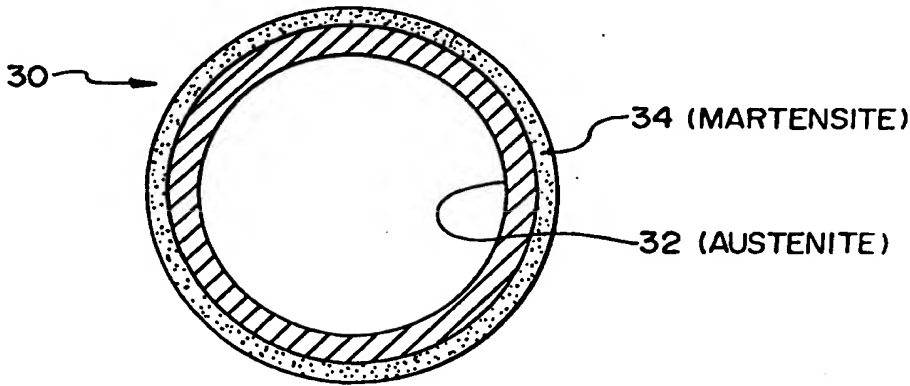
Facsimile No.: (41-22) 740.14.35

Authorized officer:

J. Zahra

Telephone No.: (41-22) 730.91.11

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b> <b>A61F 2/06</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 95/31945</b> <b>(43) International Publication Date:</b> 30 November 1995 (30.11.95)
<b>(21) International Application Number:</b> PCT/US95/06228 <b>(22) International Filing Date:</b> 18 May 1995 (18.05.95)  <b>(30) Priority Data:</b> 08/246,320 19 May 1994 (19.05.94) US  <b>(71) Applicant (for all designated States except US):</b> SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, MN 55311 (US).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> BURMEISTER, Paul, H. [US/US]; 8554 Quarles Road North, Maple Grove, MN 55311 (US). EUTENEUER, Charles, L. [US/US]; 1951 Lander Avenue N.E., St. Michael, MN 55376 (US). BROWN, Brian, J. [US/US]; 178 Jandel Avenue N.E., Hanover, MN 55341 (US). FORDENBAUCHER, Paul, J. [US/US]; 3015 James Avenue South, Minneapolis, MN 55408 (US). VRBA, Anthony, C. [US/US]; 1266 88th Place North, Maple Grove, MN 55369 (US).  <b>(74) Agents:</b> ARRETT, Oliver, F. et al.; Vidas, Arrett & Steinkraus, Suite 1540, 920 Second Avenue South, Minneapolis, MN 55402 (US).		<b>(81) Designated States:</b> CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i> <i>With amended claims.</i>  <b>Date of publication of the amended claims:</b> 1 February 1996 (01.02.96)
<b>(54) Title:</b> IMPROVED TISSUE SUPPORTING DEVICES  <b>(57) Abstract</b> <p>A new multiple component stent (10) which allows for initial self-expansion and subsequent deformation to a final enlarged size. In one embodiment, stent (10) comprises a first resilient element (12) and a second deformable element (14). In another embodiment, stent (30) is made of a first austenite component (32) and a second martensite component (34).</p> <div data-bbox="565 1129 1469 1512"></div>		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
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FR	France			VN	Viet Nam
GA	Gabon				

**AMENDED CLAIMS**

[received by the International Bureau on 28 December 1995 (28.12.95);  
new claims 22-30 added; remaining claims unchanged (1 page)]

deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite phase portion from martensite back to austenite to self-expand the stent back to the austenite phase portion predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenite superelastic portion, the shape memory of the superelastic austenitic portion tending to form the austenitic portions of the stent to the fabricated diameter parent shape due to its shape memory, with the martensitic portions remaining in the deployment shape, additional recovery back toward the stent fabricated diameter parent shape can be assisted by an external force deforming the martensitic portion without slip deformation to an enlarged stent diameter beyond that of the self-expanded austenitic portion diameter, but not greater than the stent fabricated diameter parent shape.

22. The stent of claim 20 wherein the alloy is a NiTi nitinol alloy.
23. The stent of claim 22 wherein the alloy compositions is about 50Ni/50Ti atomic weight percent.
24. The stent of claim 20 wherein the alloy is a cold worked alloy.
25. The stent of claim 20 wherein the alloy is NiTi (nitinol).
26. The stent of claim 20 wherein the alloy is a prestrained alloy.
27. The stent of claim 26 wherein the alloy is NiTi (nitinol).
28. The stent of claim 20 wherein the alloy exhibits cycle amnesia.
29. The stent of claim 28 wherein the alloy is NiTi (nitinol).
30. The stent of claim 21 wherein the two phase portions comprise a single alloy.

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>S63.3-5519</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/US 95/06228</b>	International filing date (day/month/year) <b>18/05/95</b>	(Earliest) Priority Date (day/month/year) <b>19/05/94</b>
Applicant <b>SCIMED LIFE SYSTEMS, INC. et al.</b>		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (see Box I).
2. ☐ Unity of invention is lacking (see Box II).
3. ☐ The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
  - ☐ filed with the international application.
  - ☐ furnished by the applicant separately from the international application,
    - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
  - ☐ Transcribed by this Authority
4. With regard to the title, ☒ the text is approved as submitted by the applicant.  
☐ the text has been established by this Authority to read as follows:
5. With regard to the abstract,
  - ☐ the text is approved as submitted by the applicant.
  - ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:  
 Figure No. 3
  - ☐ as suggested by the applicant. ☐ None of the figures.
  - ☒ because the applicant failed to suggest a figure.
  - ☐ because this figure better characterizes the invention.



**Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)**

A new multiple component stent (10) which allows for initial self-expansion and subsequent deformation to a final enlarged size. In one embodiment, stent (10) comprises a first resilient element (12) and a second deformable element (14). In another embodiment, stent (30) is made of a first austenite component (32) and a second martensite component (34).

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 95/06228

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR,A,2 617 721 (NIPPON ZEON) 13 January 1989  see page 10, line 10 - page 14, line 33; figures 15-20 ---	6-9, 15-18, 20,21
A	GB,A,2 175 824 (BARRY) 10 December 1986  see abstract; figures ---	6,9,15, 17,20,21
A	WO,A,94 03127 (WILLIAM COOK EUROPE) 17 February 1994  see page 14, line 20 - line 34; claims 5,6; figures 1,5 --- -/--	6-9,12, 15-18, 20,21



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

20 October 1995

Date of mailing of the international search report

30. 10. 95

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
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Fax: (+ 31-70) 340-3016

Authorized officer

Klein, C

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 95/06228

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,92 19310 (ADVANCED CORONARY TECHNOLOGY) 12 November 1992  see the whole document ---	6-9, 12, 15-18, 20, 21
A	EP,A,0 364 787 (EXPANDABLE GRAFTS PARTNERSHIP) 25 April 1990 see figures 7,8 ---	13
A	EP,A,0 335 341 (EXPANDABLE GRAFTS PARTNERSHIP) 4 October 1989 see figures 7-10 ---	13
A	US,A,5 147 370 (MCNAMARA) 15 September 1992 see column 1, line 61 - line 63; claim 8 -----	18

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 95/06228

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A-2617721	13-01-89	JP-A- 1017658 DE-A- 3823060 US-A- 4969890	20-01-89 19-01-89 13-11-90
GB-A-2175824	10-12-86	NONE	
WO-A-9403127	17-02-94	AU-B- 4698493 CA-A- 2141208 EP-A- 0653924 PL-A- 307260	03-03-94 17-02-94 24-05-95 15-05-95
WO-A-9219310	12-11-92	US-A- 5197978 CA-A- 2109312 EP-A- 0585326 JP-T- 6507096	30-03-93 27-10-92 09-03-94 11-08-94
EP-A-364787	25-04-90	AU-B- 623438 AU-B- 4248589 JP-A- 2174859 US-A- 5195984	14-05-92 12-04-90 06-07-90 23-03-93
EP-A-335341	04-10-89	US-A- 5102417 AU-B- 633478 AU-B- 3174289 CA-A- 1330186 JP-A- 1299550	07-04-92 04-02-93 28-09-89 14-06-94 04-12-89
US-A-5147370	15-09-92	AU-A- 2237792 EP-A- 0588959 WO-A- 9222263	12-01-93 30-03-94 23-12-92

REC'D 09 AUG 1996

WIPO

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>S63.3-5519</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/US 95/ 06228</b>	International filing date (day/month/year) <b>18/05/1995</b>	Priority date (day/month/year) <b>19/05/1994</b>
International Patent Classification (IPC) or national classification and IPC <b>A61F2/06</b>		
Applicant <b>SCIMED LIFE SYSTEMS, INC. et al.</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


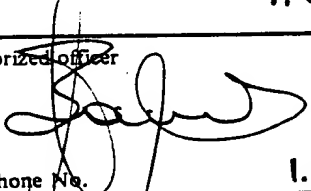
2. This **REPORT** consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consists of a total of 7 sheets.

3. This report contains indications and corresponding pages relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand <b>11/12/1995</b>	Date of completion of this report <b>7. 08. 96</b>
Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer  Telephone No. <b>I. Sampatakos</b>

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I. Basis of the report

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1. This report has been drawn up on the basis of (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

☐ the international application as originally filed.

☒ the description, pages 2, 3, 6-13 \_\_\_\_\_, as originally filed,  
pages \_\_\_\_\_, filed with the demand,  
pages 1, 1a, 4, 5 \_\_\_\_\_, filed with the letter of 15.04.96,  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_,

☒ the claims, Nos. \_\_\_\_\_, as originally filed,  
Nos. \_\_\_\_\_, as amended under Article 19,  
Nos. \_\_\_\_\_, filed with the demand,  
Nos. 1-19 \_\_\_\_\_, filed with the letter of 01.07.96,  
Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_,

☒ the drawings, sheets/fig 1/13-13/13 \_\_\_\_\_, as originally filed,  
sheets/fig \_\_\_\_\_, filed with the demand,  
sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

2. The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_.  
☐ the claims, Nos. \_\_\_\_\_.  
☐ the drawings, sheets/fig \_\_\_\_\_.

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-19 _____	YES
	Claims _____	NO
Inventive Step (IS)	Claims 1-19 _____	YES
	Claims _____	NO
Industrial Applicability (IA)	Claims 1-19 _____	YES
	Claims _____	NO

2. CITATIONS AND EXPLANATIONS

The basic aspect of the subject-matter of Claim 1 is the combination of two well known principles in the field of stents, namely starting from a self-expanding "Wallstent"-stent to improve it so as to impart to it also properties of a plastically deformable stent (like the well known "Palmaz"-stent) or vice-versa. Although it is irrelevant from which of these types of stents a problem-solution approach should start, it appears more reasonable to start from a self expanding stent, since, at least in the starting application phase of the claimed stent, which is also the most important task of the whole treatment, namely to dilate the artery, the self-expansion is the predominant aspect. Thus e.g. document WO 94/03127 could be used as the nearest prior art for Claim (since no typical "Wallstent"-stent document is included in the search report), this document disclosing in addition to thermally activated shape memory stents also "normal" self-expanding ones, see page 13, line 34 to page 14, line 3.

The problematic of the whole application is well de-

scribed on page 1 ending with the aim of the application namely to combine the advantages of both known types of stents, see page 1, lines 31-32. This is achieved by the features of Claim 1 clearly stating that the stent comprises two different types of portions each of which have a defined different behaviour and which portions are combined so as to impart to the composite product a mixture of both advantages.

The idea appears indeed simple but since no indication whatsoever about such a combination can be found in the documents of the search report and since furthermore the effect achieved by this combination appears to be important, not only novelty (Art. 33(2) PCT), but also an inventive step (Art. 33(3) PCT) has to be recognized in the subject-matter of Claim 1.

Claims 2-19 are directly dependent from Claim 1 and fulfil therefore also the requirements of novelty and inventive step.



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VII. Certain defects in the international application

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The following defects in the form or contents of the international application have been noted:

Since reference signs in parentheses have not been inserted in the claims to increase their intelligibility, the requirements of Rule 6.2(b) PCT is not met. This applies to both the preamble and characterising portion.

The requirements of Rule 6.3(b) PCT are also not met, since the independent claim is not cast in the two part form, with those features which in combination are part of the prior art being placed in the preamble.

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claim 1 lacks clarity in view of its starting phrase "As a tissue supporting device a constrainable, ...member ...", since it puts particular emphasis on the use in which the device is to be put and not on the structural features thereof. A wording like "A constrainable tissue supporting device comprising a ... member" could be used to overcome such a deficiency.
2. Claim 11 lacks clarity according to Art. 6 PCT as for the newly introduced term "**permanent** self-expanding stent", since it is not clear what has to be understood under the term "permanent". Is it a time aspect or any other idea like temperature conditions which are relevant in view of the other features of this claim referring to the temperature transformation of shape memory alloys? Depending on what the interpretation of this term would be, also an objection under Art. 34(2)(b) could apply to this amendment. This term should therefore either have been clarified on the basis of the original description or deleted.
3. The use of the term "nitinol" in Claim 9 and throughout the whole description, regardless whether it is a trade mark specially provided for a stent or for any other article or a simple name for a non protected product or material, causes a lack of clarity in the sense of Art. 6 PCT and the Guidelines PCT/GL/3-Chapter III-4.5b, since it is not exactly known what "nitinol" is. Such a term is for instance not included in the "Chambers Science and Technology Dictionary". Therefore, instead of the said term the term "TiNi-alloy" should have been used.

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 95/06228

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR,A,2 617 721 (NIPPON ZEON) 13 January 1989  see page 10, line 10 - page 14, line 33; figures 15-20 ---	6-9, 15-18, 20,21
A	GB,A,2 175 824 (BARRY) 10 December 1986  see abstract; figures ---	6,9,15, 17,20,21
A	WO,A,94 03127 (WILLIAM COOK EUROPE) 17 February 1994  see page 14, line 20 - line 34; claims 5,6; figures 1,5 ---  -/--	6-9,12, 15-18, 20,21



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

20 October 1995

Date of mailing of the international search report

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# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 95/06228

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,92 19310 (ADVANCED CORONARY TECHNOLOGY) 12 November 1992  see the whole document ---	6-9, 12, 15-18, 20, 21
A	EP,A,0 364 787 (EXPANDABLE GRAFTS PARTNERSHIP) 25 April 1990 see figures 7,8 ---	13
A	EP,A,0 335 341 (EXPANDABLE GRAFTS PARTNERSHIP) 4 October 1989 see figures 7-10 ---	13
A	US,A,5 147 370 (MCNAMARA) 15 September 1992 see column 1, line 61 - line 63; claim 8 -----	18

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 95/06228

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A-2617721	13-01-89	JP-A- 1017658 DE-A- 3823060 US-A- 4969890	20-01-89 19-01-89 13-11-90
GB-A-2175824	10-12-86	NONE	
WO-A-9403127	17-02-94	AU-B- 4698493 CA-A- 2141208 EP-A- 0653924 PL-A- 307260	03-03-94 17-02-94 24-05-95 15-05-95
WO-A-9219310	12-11-92	US-A- 5197978 CA-A- 2109312 EP-A- 0585326 JP-T- 6507096	30-03-93 27-10-92 09-03-94 11-08-94
EP-A-364787	25-04-90	AU-B- 623438 AU-B- 4248589 JP-A- 2174859 US-A- 5195984	14-05-92 12-04-90 06-07-90 23-03-93
EP-A-335341	04-10-89	US-A- 5102417 AU-B- 633478 AU-B- 3174289 CA-A- 1330186 JP-A- 1299550	07-04-92 04-02-93 28-09-89 14-06-94 04-12-89
US-A-5147370	15-09-92	AU-A- 2237792 EP-A- 0588959 WO-A- 9222263	12-01-93 30-03-94 23-12-92